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Report Highlights:

Although public opinion in France is generally opposed to products derived from biotechnology, the livestock industry is dependent upon imported genetically engineered (GE) products to meet its feed needs. France has no commercial production or field trials of GE crops, but some laboratory research is being conducted in the country. The French administration is conflicted on the way innovative biotechnologies should be regulated. The seed industry and the main farm organizations have developed a detailed position in favor of innovative biotechnologies, while anti-biotech groups have conducted a few actions against them. Public awareness is low. As for animal biotechnology, it is mainly used for medical research purposes.

Executive Summary:

Agricultural biotechnology is a very sensitive and controversial subject in France. Anti-biotech groups actively campaign against it and they have a strong influence on public opinion, which is generally opposed to products derived from biotechnology. There is better acceptance among grain producers, animal feed compounders, and scientists. Scientists and some decision-makers express growing concern with the precedence of politics over science. In 2017, the National Assembly voted a resolution on this subject.

France is active in research and uses both genetic engineering and innovative biotechnologies in labs. However, the country is more advanced in medical and industrial biotechnology than in agricultural biotechnology. No field trials are being carried out in France, due to the destruction of test plots by activists. Research is not expected to lead to the commercialization of plants produced through genetic engineering or innovative biotechnologies in the next five years.

France does not produce any agricultural goods derived from biotechnology for commercial purposes. However, the country imports GE feed, mainly soybeans and soybean meal from South America and rapeseed (canola) from Canada. French imports from the United States consist of soybeans and soybean meal. Domestic non-GE soybean production remains marginal relative to imports but is increasing due to incentive policies. The French Government, the main farm union, and anti-biotech activists are all opposed to the European Commission's proposal that would allow member states to ban the use of EU-authorized GE products. This proposal is contrary to single market principles and incompatible with international obligations of the EU.

France's agricultural biotechnology policies are part of the European Union's (EU) policy and regulatory framework. National legislation is more restrictive than EU legislation and includes a compulsory field register for GE crop fields and voluntary non-biotech labeling on food products. Regarding intellectual property, France supports the plant certificate system rather than the patent system. The government is opposed to using biotechnology in animal breeding, due to ethical and animal welfare concerns.

The Ministry of Agriculture and the Ministry of Environment have conflicting views on how innovative biotechnologies should be regulated. Both are waiting for the answers of the European Court of Justice to the questions asked by the French Supreme Court in October 2016. The French biosafety authority (the High Council for Biotechnology) has released two reports on innovative biotechnologies and keeps working on this subject. After more than a year of hearings and investigations in a number of countries, the French Parliament published a pro-science report on innovative biotechnologies in March 2017. The seed industry and the main farm organizations have developed a detailed position in favor of these technologies, while anti-biotech groups have conducted a few actions against them. Public awareness of potential agricultural applications is low. France is conducting limited research on this subject and is constrained by the absence of field trials.

France elected a new president (Mr. Macron) in May 2017. The positions he expressed during the campaign are in line with these of the previous administration. The current situation with imports but no cultivation is unlikely to change in the short term. The policy that aims at partly substituting imports

with subsidized local production is expected to continue. Like the previous administration, Mr. Macron says he is in favor of research; it remains to be seen whether this position will translate into action.

Acronyms used in this report are the following:

ANSES	Agency for Food, Environmental and Occupational Health and Safety
CIRAD	French Agricultural Research Centre for International Development
CNRS	National Center for Science Research
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
EFSA	European Food Safety Authority
EU	European Union
GE	Genetically Engineered
HCB	High Council for Biotechnology
INRA	French National Institute for Agricultural Research
LLP	Low Level Presence
MT	Metric Ton
NGOs	Non-Governmental Organizations
ODM	Oligonucleotide-Directed Mutagenesis
SDN	Site-Directed Nuclease
TALEN	Transcription Activator-Like Effector Nuclease
ZFN	Zinc-Finger Nuclease

Glossary:

Note: The mention "in French" after a link means that this link returns a page that is only available in French.

[&]quot;Genetic Engineering" means transgenesis.

[&]quot;Innovative biotechnologies" is a synonym of New Breeding Techniques (NBTs). It excludes transgenesis.

Table of Contents

	FER 1 – PLANT BIOTECHNOLOGY	
PAR	Τ A – PRODUCTION AND TRADE	5
a)	PRODUCT DEVELOPMENT	5
b)	COMMERCIAL PRODUCTION	7
c)	EXPORTS	7
d)	IMPORTS	7
e)	FOOD AID	10
f)	TRADE BARRIERS	11
PAR	T B - POLICY	12
a)	REGULATORY FRAMEWORK	12
b)	APPROVALS	
c)	STACKED EVENT APPROVALS	14
d)	FIELD TESTING	
e)	INNOVATIVE BIOTECHNOLOGIES	
f)	COEXISTENCE	
g)	LABELING	
h)	MONITORING AND TESTING	
i)	LOW LEVEL PRESENCE POLICY	
j)	ADDITIONAL REGULATORY REQUIREMENTS	
k)	INTELLECTUAL PROPERTY RIGHTS (IPR)	
1)	CARTAGENA PROTOCOL RATIFICATION	
m)		
PAR	Γ C - MARKETING	
a)	PUBLIC/PRIVATE OPINIONS	
a)	MARKET ACCEPTANCE/STUDIES	25
СНАРТ	ΓER 2 – ANIMAL BIOTECHNOLOGY	25
PAR	Γ D – PRODUCTION AND TRADE	
a)	PRODUCT DEVELOPMENT	25
b)	COMMERCIAL PRODUCTION	26
c)	EXPORTS	
d)	TRADE BARRIERS	
PAR	T E – POLICY	
a)	REGULATORY FRAMEWORK	
b)	INNOVATIVE BIOTECHNOLOGIES	
c)	LABELING AND TRACEABILITY	
d)	INTELLECTUAL PROPERTY RIGHTS	
e)	INTERNATIONAL TREATIES AND FORUMS	
PAR	T F – MARKETING	
a)	PUBLIC/PRIVATE OPINIONS	
b)	MARKET ACCEPTANCE/STUDIES	28

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

France is active in research and uses both genetic engineering and innovative biotechnologies in lab. However, the country is more advanced in medical and industrial biotechnology than in agricultural biotechnology.

As far as agricultural biotechnology is concerned, the level of activity of France depends on the technique used. The country:

- conducts very limited research involving transgenesis;
- has one research project on innovative biotechnologies and may launch another one in 2018;
- is active in genomic selection.

Research is not expected to lead to the commercialization of plants produced through genetic engineering or innovative biotechnologies in France in the next five years. However, a few French companies develop plants for non-EU markets using these techniques.

France elected a new president (Mr. Macron) in May 2017. During the campaign, he expressed his position as follows: "It is essential to conduct public and private research. I am in favor of studying the potential of transgenesis and innovative biotechnologies in lab and in confined spaces for agricultural and pharmaceutical purposes." It is unclear at this stage whether this position will translate into action and whether "confined spaces" include confined field trials.

• France conducts very limited research in agricultural biotechnology involving transgenesis.

Research in agricultural biotechnology is not expected to lead to the commercialization of new varieties of GE plants in the next five years because:

- Public institutions are constrained by the absence of field trials and a lack of political support for research involving genetic engineering. They cannot afford the regulatory costs associated with commercialization.
- The private sector's interest in developing varieties of GE plants suitable for cultivation in the European Union has waned. Repeated vandalism of test plots by activists, together with the uncertainty and delays of the EU approval process, makes genetic engineering an unattractive investment.
- Regulatory uncertainty hinders the development of innovative biotechnologies.

Public institutions are conducting some research and seed companies know that it is vital for them to master innovative biotechnologies. However, both face regulatory uncertainty and are constrained by the absence of field trials.

France has one research project in agricultural biotechnology that involves innovative techniques, the <u>Genius project</u>. It is a public-private partnership that aims at demonstrating the feasibility of genome

editing (meganucleases, TALENs, CRISPR-Cas9) in various plant species (corn, wheat, rice, rapeseed tomato, potato, apple tree, poplar tree, rose tree). The traits concerned are resistance to pathogens, salinity tolerance, and increased biomass production.

In October 2015, France presented an "Innovation Plan for 2025," which includes a research project aiming at mastering innovative biotechnologies. This project would be launched in 2018 and last until 2021. It would bring together public research institutes and private companies. The plants developed would have better resistance to diseases, water or nitrogen efficiency, or tolerance to climate change. The expected output is:

- A strong knowledge of innovative biotechnologies, especially gene editing and meiotic recombination, when applied to the main crops. This would include phenotypic analysis in the fields.
- Strategies to improve the efficiency of innovative biotechnologies;
- Cost benefit analyses of innovative biotechnologies and of the plants produced through innovative biotechnologies;
- A knowledge of the expected performance of the plants produced through innovative biotechnologies when cultivated in the fields.

The project includes field trials. If it is launched, it remains to be seen how the risk of destruction of field trials by anti-biotech groups will be managed.

• France uses genomics in plant breeding.

Unlike transgenesis and innovative biotechnologies, genomic tools are not controversial and both public labs and private seed companies are active in this field.

• A few French companies develop biotech plants for non-EU markets.

A few French companies develop plants produced through transgenesis or innovative biotechnologies and intend to commercialize them outside Europe; their biotech research facilities are based outside France. For instance, Calyxt is the subsidiary of Cellectis that focuses on agricultural biotechnology. Calyxt uses the TALEN technology (gene editing) to produce plants with improved preservation or nutritional properties. The Cellectis company was created in France but Calyxt is based in Minnesota, United States.

France conducts laboratory research for medical applications.

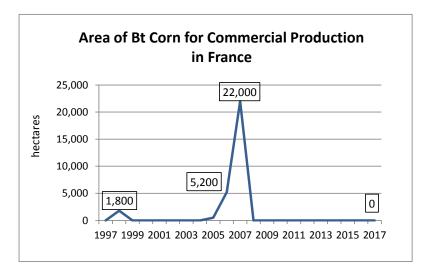
GE plants and plant cells are used to develop proteins of pharmaceutical interest in-lab. Proteins whose structure is simple, such as insulin and growth hormone, can be produced by GE microorganisms and some of them are commercialized. GE plants and plant cells are used to develop more complex molecules for research purposes (vaccines, antibodies, enzymes).

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¹ See the <u>Innovation Plan for 2025</u> in French

b) COMMERCIAL PRODUCTION

France does not produce any GE crops for commercial purposes and this situation is unlikely to change in the medium term. The new president elected in 2017, Mr. Macron, said during the presidential campaign that he would not allow the cultivation of GE crops.



MON810 Bt corn is currently the only GE plant approved for cultivation in the EU and, since 2008, its cultivation has been banned in France (see Part B - Policy).

There were 1,800 hectares of GE corn planted in France in 1998, then none during the European *de facto* moratorium between 1999 and 2004. Cultivation was reinitiated between 2004 and 2007 and reached 22,000 hectares before dropping to zero in 2008.

The technical results obtained by corn growers in 2006, with higher yields and lower mycotoxin content than conventional corn, explain the rapid expansion of the planted area between 2005 and 2007.

c) EXPORTS

France does not export any GE plants.

d) IMPORTS

The bulk of France's imports of biotech products consist of soybeans and soybean meal from the Americas, used as animal feed ingredients. The share of GE products out of total imports is estimated at more than 80 percent. French non-GE soybean production is expected to increase in the coming years but it remains marginal relative to imports. France also imports GE rapeseed.

Trade data do not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. The table below gives the share of GE crops in total soy and rapeseed production in France's main supplier countries.

Share of GE Crops in Total Production in 2015

Soy		
Argentina	99 %	
Brazil	93 %	
Canada	62 %	
Paraguay	96 %	
United States	94 %	

Rapeseed			
Canada	95 %		
Australia	17 %		

Source: USDA FAS GAIN reports, latest data available

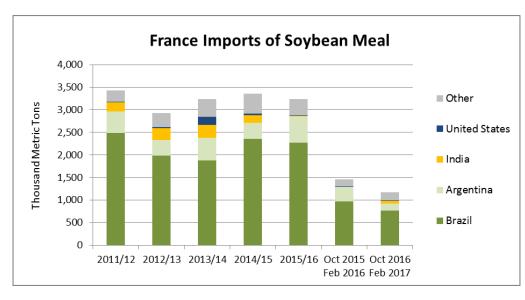
• France imports around 4 million metric tons of soybean products per year.

France is a major importer of soybean products to feed animals in its livestock and poultry sectors. Domestic production of soybeans and substitutes is limited, and there is a strong demand for protein to meet basic requirements of compound feed formulations. The decision of French importers on where to source soybean products from year to year is primarily based on price.

In the last five years, France imported 3.2 million metric tons (MT) of soybean meal per year on average. The chart below gives the evolution of French imports between 2011/12 and the first ten months of 2016/17. Brazil remains the leading supplier with a 70 percent market share in 2015/16. ²

Soybean meal imported in France includes on average:

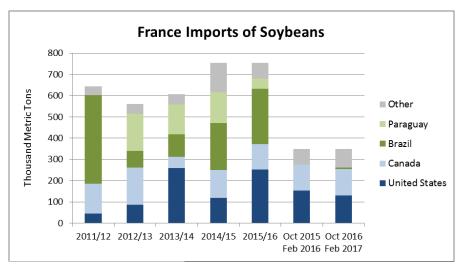
- 75 percent of standard product, not tested, and labeled as GE;
- 5 percent of Hard Identity Preserved product, traced back from the field to guarantee that it is not GE;
- the 20 percent remaining products include three categories:
 - o product labeled as GE and that contain less than 0.9 percent of GE soy (when PCR-tested);
 - o product not labeled as GE and that contain less than 0.9 percent of GE soy (when PCR-tested);
 - o Soft Identity Preserved product, traced back from the crushing plant to guarantee that it is not GE.



 $^{^2}$ 2015/16 marketing year for soybeans is October 2015 to September 2016 $\,$

Source: Global Trade Atlas

In the last five years, France imported on average 660 thousand MT of soybean per year (see graph below). The U.S., Brazil, Canada, and Paraguay are France's leading suppliers.



Source: Global Trade Atlas

Soybean meal is the main oilseed meal for feed in France. Soybean meal and rapeseed meal are expected to account for 45 and 33 percent of total meal consumption, respectively, in 2016/17. The consumption of sunflower meal has increased in recent years due to its improved digestibility, low price, and supply availabilities from the Black Sea area (Ukraine and Russia). In MY 2016/17, it accounted for 20 percent of vegetable meals consumed in animal feed.

The demand for non-biotech soybean meal is estimated at 20 percent of the total market in France. It is mainly supplied by domestically-grown soybeans and imports of soybean products from Brazil and India. It has become increasingly difficult to source non-biotech soybeans during the last ten years, because available supplies are small and it is costly to avoid the mixing of GE and non-GE products during transportation and storage. As a consequence, there is a premium for non-biotech soybeans, which varies between 60 and 100 euros per MT.

• France is trying to reduce its dependence on imported proteins.

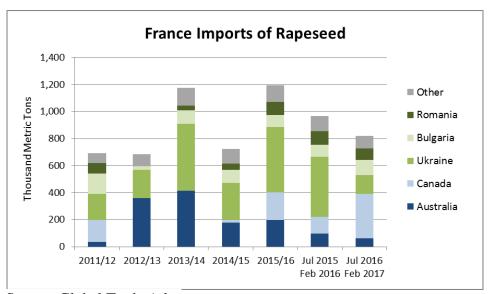
French soybean production remains marginal relative to imports but it is expected to increase in the coming years, from 110 thousand MT in 2013/14 to almost 340 thousand MT in 2016/17 according to USDA's outlook. Domestic production is 100 percent non-GE as no GE soybean is allowed for cultivation in the EU. The rise in the planted area is mainly due to incentive policies:

- The 2014-2020 Common Agricultural Policy (CAP) gives incentives to produce soybeans and protein crops. Under the CAP, France has chosen to give farmers coupled supports for soybeans from 2014. Moreover, in France, soy areas can be considered as Ecological Focus Areas (EFAs) under the CAP, and farmers that have a certain amount of EFAs receive higher direct payments.
- Several French regions subsidize local production of soy and protein crops.

France's new administration is planning to continue this policy. Until now, public policies have led to a rise in soybean production in France but soybean imports have not declined.

• France imports GE rapeseed from Canada.

In the last five years, France imported between 680,000 and 1,200,000 MT of rapeseed per year. In 2015/16, 17 percent of France's imports came from Canada, where 95 percent of rapeseed is GE; and 16 percent came from Australia, where 17 percent of rapeseed is GE.³



Source: Global Trade Atlas

e) FOOD AID

France provides food aid in the form of food, money, equipment, seeds, or veterinary services. The country provides both planned aid (*Aide alimentaire programmée*) and emergency aid (*Fonds humanitaire d'urgence*) when a crisis occurs, whether it is climatic, economic, social, or political.

Aid is delivered:

- via international organizations (more than 75 percent of the total budget) such as the World Food Program and the International Committee of the Red Cross;
- via non-governmental organizations (NGOs; 15 to 20 percent of the total budget) such as Action Against Hunger;
- directly (5 to 10 percent of the total budget).

This aid does not include GE products.

In 2013, the total budget of French food aid was 35 million euros. It was delivered to Africa (Burkina Faso, Central African Republic, Chad, Congo, Ethiopia, Kenya, Madagascar, Mali, Mauritania, Niger, Somalia, South Sudan, and Sudan), the Middle East (Afghanistan, Iran, Iraq, Jordan, Lebanon,

³ 2015/16 marketing year for rapeseed: July 2015 to June 2016

Palestine, Syria, Turkey, and Yemen), Haiti, Myanmar and North Korea. A map that provides the budget by country is available on the website of the French Ministry of Foreign Affairs (in French).

France is still influential in Africa, especially in North and West African countries that used to be part of France's colonial empire. In these countries, France spreads negative messages about agricultural biotechnology and the potential of the technology to help fight hunger.

f) TRADE BARRIERS

Cultivation Ban

Cultivation of GE corn has been banned in France since 2008 and the situation is unlikely to change in the medium term. Between 2007 and 2014, three decrees that banned cultivation were successively released by the Government and cancelled by the Supreme Court because they were not legal; then a law (in French) that banned cultivation of GE corn in France was passed in June 2014.

In March 2015, with the support of the French Government, the EU released Directive (EU) 2015/412 that allows member states to restrict or ban the cultivation of EU-authorized GE plants in their territory for reasons other than risks to human health, animal health or the environment. For more information, please see USDA EU-28 Agricultural Biotechnology Annual report.

Under Article 26c of the Directive – transitional measures – France demanded in September 2015 that the French territory be excluded from the geographical scope of the authorizations of cultivation for eight GE corn varieties. ⁴ The companies that developed these varieties did not oppose this decision within the legal delay of 30 days and the geographical scopes of the authorizations were adjusted accordingly. The transcription of Directive (EU) 2015/412 into French Law was then released in December 2015. ⁵

• Imports Ban

In April 2015, the European Commission released a proposal for a regulation that would allow member states of the EU to restrict or ban the use of EU-authorized GE crops or products. Opt-outs would have to be based on reasons other than those assessed at the EU level, since the review by the European Food Safety Authority (EFSA) would have already deemed the crops or products to be safe. For more information, please see USDA <u>EU-28 Agricultural Biotechnology Annual</u> report.

France opposed the opt-out for use proposal because it is contrary to single market principles and incompatible with international trade agreements. Moreover, if the proposal were adopted, France would be placed in the uncomfortable position of facing great pressure to ban the use of GE products from anti-biotech groups. Such a ban would be detrimental to the already stressed French livestock and poultry sectors, since it would be very difficult and costly to source sufficient non-GE feed ingredients to meet their needs. Given this situation, French policy makers do not want to be in the position of having the responsibility for banning GE products or not.

⁴ The notifications are available on the European Commission's website

⁵ Only available in French - <u>Loi n° 2015-1567 du 2 décembre 2015</u> portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la prévention des risques, Titre IV

The main farm union in France (FNSEA) openly opposes the proposal, saying that "the European Union is a common market so we need common rules." Anti-biotech activists criticize the proposal too, saying that member states that want to ban the use of GE products would be unable to find justifications compatible with the EU legislation and the international obligations of the EU.

• Reformulation

Since the European regulation on biotech traceability and labeling for food and feed has been implemented in France, the French food industry and supermarket chains have reformulated to exclude potential GE ingredients, such as corn starch, soy lecithin, and soy oil.

PART B - POLICY

a) REGULATORY FRAMEWORK

France operates under the biotechnology regulatory framework of the EU. For more information about the European framework, please refer to USDA EU-28 Agricultural Biotechnology Annual report.

i. Responsible government ministries and their role in the regulation of GE plants

Several ministries are involved in oversight of GE plants in France:

- The Ministry of Environment has the lead;
- The Ministry of Agriculture deals with cultivation and coexistence, as well as plant and animal health issues;
- The Ministry of Economy's Fraud Control Office (DGCCRF) controls imported products and is involved in low-level presence (LLP) issues;
- The Ministry of Research covers public research programs;
- The Ministry of Health is involved in the impact on human health.

These ministries have a joint website (in French) to communicate on biotechnology policies and regulations.

ii. Role and membership of the biosafety authority

The High Council for Biotechnology (<u>HCB</u>) was established by the Biotech Bill of 2008. Its composition and functions were modified in September 2014. As part of the European approval framework, it is in charge of evaluating environmental risks of biotech products under review for approval for cultivation or commercialization. Since September 2014, it is no longer responsible for health risks.

The HCB is composed of a science committee (scientists) and a socio-economic and ethics committee (legal experts, researchers, farmers, representatives of the seed industry, consumer associations, and environmental NGOs). Both committees review biotech dossiers and provide their respective conclusions and recommendations to the Government of France and to the European Food Safety

⁶ See decree (in French), September 2014

Authority (EFSA).

France's National Agency for Food, Environmental and Occupational Health and Safety (ANSES) is in charge of reviewing the food safety aspects of GE crops and their derived products in food and feed.⁷ It transmits its conclusions and recommendations to EFSA, as part of the European approval framework.

iii. Political factors influencing regulatory decisions related to plant biotechnology

Biotech opponents have played an important part in the adoption of the regulatory decisions related to plant biotechnology, both directly and through their impact on public opinion (see Part C. Marketing — b. Public / Private Opinion).

iv. Distinctions between regulatory treatments of the approval for food, feed, processing and environmental release

Since the beginning of the commercialization of biotech plants in the early 1990's, France has authorized biotech imports (due to the need for protein-rich ingredients in animal feeds), but restricted research and banned cultivation of biotech crops.

The process for approval of biotech products is carried out at the EU level, but the French Government has some latitude to implement its own regulations as long as they comply with EU regulations. A large number of biotech events have been approved for feed and food use at the European level and have not been questioned by French authorities. However, France has banned the cultivation of MON810 corn, even though it was approved by the EU.

v. Legislation and regulations with the potential to affect U.S. trade

Legislation and regulations with the potential to affect U.S. trade include the national ban on GE corn cultivation and the non-biotech labeling system implemented at the national level.

vi. Timeline followed for approvals

European Directive <u>2001/18/EC</u> provides the framework for the deliberate release into the environment of GE plants. Regulation (EC) No <u>1829/2003</u> covers the authorization for placing GE products on the market for food and feed. For more information, please refer to USDA <u>EU-28 Agricultural</u> <u>Biotechnology Annual</u> report.

b) APPROVALS

• Food, feed, processing

All of the biotech events approved for feed and food use in the EU under Regulation EC 1829/2003 are authorized in France. The full list of these products, including events for which an authorization procedure is pending, is available on the European Commission's website.

⁷ See ANSES <u>website</u> dedicated to agricultural biotech products (in English)

• Cultivation

MON810 corn is the only GE plant approved for cultivation in the EU. Its cultivation is banned in France under a national law (in French) and under Directive (EU) 2015/412.

c) STACKED EVENT APPROVALS

The regulation in place in France is that of the EU. The risk assessment follows the provisions of Regulation (EU) No 503/2013, Annex II. The applicant shall provide a risk assessment of each single event or refer to already submitted applications. The risk assessment of stacked events shall also include an evaluation of (a) stability of the events, (b) expression of the events, and (c) potential interactions between the events.

d) FIELD TESTING

In France, the deliberate release of GE plants in open environments for research purposes is subject to prior approval by the government, usually through the Ministry of Environment. The government must consider the opinion of the HCB regarding possible risks for public health and the environment before granting an authorization. The government must also hold a public consultation on the Internet and provide advance notice to the local authorities of areas where test plots for GE plants are located. The authorization may be amended or suspended if justified by new information.

• Open-field testing

No open-field testing is currently conducted in the country due to repeated destruction of test plots by activists. France used to have the highest number of open-field test plots for GE plants in Europe, but continued destruction of these plots by activists has discouraged both public and private organizations from conducting research in open fields. Some of the labs that develop biotech plants in France conduct field tests in other countries.

The last experimental plot in France was a GE Poplar tree being tested by the National Institute for Agricultural Research (INRA). Their multi-year permit for open-field testing was not renewed by the Ministry of Agriculture and all the trees were destroyed in 2013. The Ministry of Agriculture was supposed to make its decision based on the advice of the HCB. However, the HCB struggled in giving a clear opinion on the renewal of the permit, since its two committees disagreed:

- The **science committee**, made up of 40 scientists, concluded that there was "no risk for human or animal health or the environment," and proposed to continue the experiment.
- The **socio-economic and ethical committee**, which gathers jurists, farmers, representatives of the seed industry, consumer associations, and environmental NGOs, opined that the objectives of the research were too vague and that it raised "many socio-economic and ethical questions." This committee consequently proposed to put an end to the test.

⁸ Environmental Code <u>art. L533-3 (in French)</u>

Despite the destruction of its last remaining open-field test plot, INRA expressed its wish to continue research on GE crops.⁹

e) INNOVATIVE BIOTECHNOLOGIES

• The High Council for Biotechnology (HCB) is working on innovative biotechnologies.

In January 2016, the HCB released its first two reports on innovative biotechnologies:

- A <u>scientific report (see pages 95 to 107 in English)</u> that gives a description of each technique and of its possible applications; explains what is at stake regarding the regulation of innovative biotechnologies; analyses the questions raised, technique by technique (for instance the ability to detect the genetic modification or the possible agronomic applications of innovative biotechnologies); and answers the question "Should the resulting organisms be regulated as 'GMOs' under Directive 2001/18/EC?," technique by technique (see the table below).
- An economic, ethical and social report (see pages 106 to 117 in English) that presents the different and sometimes opposite points of view of farm unions, the seed industry, retailers, and NGOs. This report also provides two legal analyses that reach opposite conclusions. It concludes that the way to regulate the organisms produced through innovative biotechnologies "will be dictated essentially by policy considerations, in accordance with a set of criteria that are yet to be determined. The European Commission has pointed out, however, that without a legal amendment to the texts, which is clearly a policy matter, only the European Court of Justice has the power to issue a ruling."

HCB Scientific Report on Innovative Biotechnologies, January 2016 - Should the organisms produced through innovative biotechnologies be regulated as "GMOs?"

Technique	Should the resulting organisms be regulated as "GMOs" under Directive 2001/18/EC?	Why?
SDN-1 SDN-2 ODM	No	These techniques generate modifications and products identical to those obtained by conventional mutagenesis. They should be classified the same way as mutagenesis (Annex 1B of Directive 2001/18/EC).
SDN-3	Yes if the sequence introduced is exogenous to the plant, otherwise no	If the sequence introduced is not exogenous, the modification is similar to naturally occurring duplication.
Grafting: (a) non-GE graft on GM rootstock, or	Differentiated assessment for graft and rootstock	Fruit and seed of non-GE plants derived from GE rootstock do not require specific environmental or health assessment; the rootstock should be

⁹ More information available in French on <u>INRA website</u>

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(b) non-GE graft on a rootstock produced		regulated on the basis of the technique used to produce it.
through innovative biotechnologies		
RNA-directed DNA methylation (RdDM)	No if they contain no transgenes	Epigenetic changes are observed in nature. RdDM is intended to guide such changes, but the mechanism is not different from those found in nature. If they contain no transgenes, plants with epigenetic modifications should not be subject to systematic assessment.
Agro-infiltration	No	Agro-infiltration in the narrow sense used by the European Commission does not include transformation of germ tissue and is not intended to produce GE offspring. The agrobacteria used are genetically modified micro-organisms and are therefore regulated as such.
Cisgenesis and intragenesis	No if modifications could be obtained by conventional breeding, otherwise yes	Specific molecular analysis is required. If the modification could be obtained by conventional breeding, the resulting organism should not be regulated as a GE organism.
Null segregants	No	After molecular confirmation that the modification has been removed, the resulting plant should be exempt from risk assessment and could be considered to be a plant obtained by conventional breeding.

The position of the seed industry and of the main farm unions is available in French in the economic, ethical and social report. They state that:

- Innovative biotechnologies could address a number of issues in the agricultural sector, i.e., using less fertilizer, pesticides, and water; increasing the stability of production and adapting to a changing climate; increasing production to meet rising demand; improving food quality, addressing food safety and food preservation; diversifying crops; and answering specific needs (producing drugs, biomass, cosmetics, fibers).
- Innovative biotechnologies complement and follow on from previous breeding techniques.
- Innovative biotechnologies will lead to innovations only if regulatory costs are acceptable, considering the size of target markets.
- Regulations should be based on science.
- The organisms developed using innovative biotechnologies should not be considered as "GMOs" under Directive 2001/18/EC if: (a) they could have been developed through crosses; (b) they could have been developed through mutagenesis; or (c) no exogenous heritable material is inserted in their progeny.

In April 2016, the Minister of Agriculture and the Minister of Environment sent an official request to the HCB. They asked the HCB to work on the techniques that do not produce "GMOs" according to the definition set out in Directive 2001/18/EC (see table above). For these techniques, the HCB is asked to release an opinion on the following subjects:

- detection and traceability of the plants and products;
- coexistence between biotech and non-biotech plants and products;
- direct risks to health and the environment linked to novel characteristics of the final products and measures that could be implemented to manage possible risks;
- impact of the development of innovative biotechnologies on the ability of the private sector to innovate;
- innovative biotechnologies and intellectual property;
- an analysis of the legal interpretation of the European Commission as soon as it is available;
- recommendations about the way innovative biotechnologies should be regulated; the proposals should be between those of the European catalogue (no risk evaluation, no labeling) and those of Directive 2001/18/EC (risk evaluation and labeling). Socio-economic issues should be taken into account.

The HCB is working on these subjects at the moment.

• The French administration has no official position yet; the French Supreme Court has questioned the European Court of Justice.

On October 3, 2016, the French Supreme Court (Conseil d'Etat) referred four interlocutory questions about innovative biotechnologies and mutagenesis to the European Court of Justice. In these questions, the term "mutagenesis" includes chemical and radiation mutagenesis, which have been practiced for decades, as well as innovative biotechnologies, such as oligonucleotide-directed mutagenesis and site-directed nucleases:¹⁰

- Are the organisms produced through mutagenesis "GMOs" under Directive 2001/18/EC? Which of these organisms are regulated as "GMOs" under Directive 2001/18/EC?
- Are the organisms produced through mutagenesis "GMOs" under Directive 2002/53/CE?
- If organisms produced through mutagenesis are not regulated as "GMOs" under Directive 2001/18/EC, does it mean that the member states are not allowed to set their own regulations for these organisms?
- Is the exclusion of mutagenesis from Directive 2001/18/EC consistent with the precautionary principle?

It takes on average between one year and a half and two years for the Court of Justice to answer member states' questions. Depending on the answers, the European Commission may have to amend Directive 2001/18/EC.

The decision to ask the European Court of Justice's opinion is due to the fact that nine anti-biotech groups submitted a complaint with the Conseil d'Etat in March 2015. These groups contest the fact that under an article of the French Environment Code, plants produced through traditional mutagenesis are not considered as GE. This article is a transposition of Directive 2001/18/EC. These groups also

¹⁰ The <u>decision (in French)</u> is available on the website of the Conseil d'Etat.

¹¹ Confédération paysanne, Réseau semences paysannes, Amis de la Terre France, Collectif vigilance OGM 16, Vigilance OG2M, CSFV 49, OGM dangers, Vigilance OGM 33, Fédération nature et progrès

¹² French Environment Code, <u>Article D531-2 (in French)</u>

ask for a moratorium on cultivation and sales of herbicide-resistant plants produced through mutagenesis (herbicide-tolerant rapeseed and sunflower produced through mutagenesis are grown in France). Before submitting a complaint with the Conseil d'Etat, these groups had asked the Prime Minister to change the law so that plants produced through mutagenesis are considered as GE. He had not answered.

• The French Parliament has released a pro-science report on innovative biotechnologies.

On March 29, 2017, the French Parliamentary Office for the Evaluation of Scientific and Technological Choices (Office parlementaire d'évaluation des choix scientifiques et technologiques, OPECST) released a draft pro-science report on innovative biotechnologies. This office is common to the National Assembly and the Senate, and is in charge of keeping the French Parliament informed on scientific issues by assessing the consequences of emerging scientific progress, monitoring the implementation of new technologies, and reviewing topical and controversial subjects.

OPECST's report is the result of more than a year of hearings and investigations in a number of countries including the United States. It covers agricultural applications of innovative biotechnologies as well as medical and industrial uses. It advocates for science-based and proportionate regulations, increased research and more communication to the general public. Given agricultural biotechnology is a highly politicized and very sensitive subject and the continued influence of anti-biotech groups in France, it is unlikely all of the recommendations will be implemented. However, they will be looked at by many decision makers and may lead to positive developments in the future.

Recommendations can be divided into three categories: research, regulations and communication to the general public.

First, OPECST recommends increasing public spending in biotech research and allowing field trials. They deplore that while French researchers contributed to the invention of CRISPR-Cas9, applied research is very limited in the country. They warn of a potential "brain drain" of France and the EU. They suggest creating three or four experimental areas isolated from conventional crops. They advocate for the commercialization of the fungus resistant vines developed by INRA, which would allow a reduction in pesticide use.

As far as regulation is concerned:

- They advocate for science-based and proportionate regulations that would take experience and feedback into account.
- They urge European institutions to make a decision on how to regulate innovative biotechnologies. They argue that the European Commission and the Member States should make this decision rather than the European Court of Justice.
- They think that plants produced through innovative biotechnologies should not be regulated as genetically engineered plants; and that EU regulations should be product-based, not process-based.
- They defend plant variety rights and oppose patents for genes that exist in nature.
- They propose to work on innovative biotechnologies with the Food and Agriculture Organization of the United Nations (FAO).

• They propose to reform the High Council on Biotechnology, whose two committees often disagree. They suggest transferring the missions of the science committee to the French Food Safety Agency (ANSES). The missions of the HCB would be to monitor the sanitary and environmental situation and analyze biomonitoring data.

Finally, they present several measures that could help educate the general public: organizing a national public debate on innovative biotechnologies facilitated by scientific academies, educating students, broadcasting more scientifically-focussed programs on public television

Scientific Academies work on genome editing.

The French Academy of Sciences, as a member of the European Academies Science Advisory Council (EASAC), participated in EASAC's work on genome editing. A report entitled "Genome Editing: Scientific opportunities, public interests, and policy options in the EU" was released in 2017.

In 2016, the French Academies of Agriculture and Technologies released a common position paper on genome editing (meganucleases, ODM, ZFN, TALEN, CRISPR). Their position is that "the administration should support the development of experiments, including field trials, and use the results of these experiments to build a legislative framework that includes monitoring and allows the technical advances that these techniques provide to be used. (...) These techniques can be excluded from the scope of Directive 2001/18/EC, in accordance with Annex I B."

• Anti-biotech groups have conducted several actions against innovative biotechnologies.

Small groups of people conduct actions that aim at turning public opinion against innovative biotechnologies and influencing policy-makers.

They call the plants produced through innovative biotechnologies "new GMOs" or "hidden GMOs" and want all of them, as well as the plants produced through classical mutagenesis, to be regulated as GE plants under Directive 2001/18/EC. As a result of their actions, the terms "new GMOs" and "hidden GMOs" have become widely used by the media.

They have conducted several actions since the beginning of 2016. In April 2016, seven anti-biotech organizations that are represented at the socio-economic council of the HCB organized a protest before the General Assembly of the HCB, which was cancelled, and then they resigned from the HCB. These resignations were widely covered by the media. In May, a few dozen people of the minority farm-union *Confédération paysanne* protested on a site owned by the main French seed company.

f) COEXISTENCE

French legislation requires that GE plants only be grown, sold, or used "in a manner that respects the environment and public health, agricultural structures, local ecosystems, production and commercial channels labeled as 'without GE plants,' and with full transparency."¹³ It also guarantees the "freedom

¹³ Environmental Code art. L531-2-1 (in French)

to consume and produce with or without GE plants." In order to promote these goals, French legislation aims to limit the spread of GE plants beyond their intended fields. It thus states that the cultivation, harvest, storage, and transportation of GE crops should be subject to certain technical rules established by the Minister of Agriculture, such as distances between GE crops and other fields. ¹⁴

In addition to these rules, legislation provides for "biological monitoring" of French territory, to observe the health of plant life and watch for possible unforeseen consequences of agricultural practices, including the use of GE plants. ¹⁵ This is coordinated by the Committee for Biological Monitoring of the Territory, which was created for that purpose by the 2008 law on GE plants. ¹⁶ This body submits an annual report to both houses of the French Parliament and can alert the government if it finds that certain unintended consequences require that special measures be taken.

French legislation provides that a GE crop cultivator will be automatically liable when the accidental spread of his plants causes economic harm to a non-GE crop cultivator. ¹⁷ If a non-GE crop cultivator ends up having to label his or her crops as GE, because of spread from a nearby field, he can seek compensation for the resulting depreciation of his crop's value. It is also mandatory for any cultivator who uses GE crops to obtain liability insurance coverage. However, insurance companies have been unwilling to cover GE crops in France.

In practice, when GE corn was grown in France, a buffer zone of 24 rows and 50 meters was put in place around the fields. Research programs were conducted to study the feasibility of coexistence in real field conditions (from seed to storage facilities), good harvesting and processing practices aimed at managing the coexistence of GE and non-GE sectors affordably were defined, and a guide for GE corn cultivation was released.

g) LABELING

• European Mandatory Labeling of GE Products

Labeling in France complies with EU regulations that require food and feed produced from or containing GE products to be labeled as such. For more information, please see USDA <u>EU-28</u> <u>Agricultural Biotechnology Annual</u> report.

The French Fraud Control Office of the Ministry of Economy, Finance and Industry (DGCCRF) enforces compliance with the regulation. An explanation on biotech labeling regulation is available on the Fraud Control Office's <u>website (in French)</u>.

• France's Voluntary "GE Free" Labeling System

In addition to EU regulations, a "GE Free" labeling system has been in place at the national level since 2012. This system is based on a 2012 <u>decree (in French)</u>. It only applies to food produced in France. Imported products are not concerned. It states that:

¹⁴ Rural Code art. L663-2 (in French)

¹⁵ Rural Code art. L251-1 (in French)

¹⁶ Comité de surveillance biologique du territoire (in French)

¹⁷ Rural Code art. L663-4 (in French)

- Plant products can be labelled as "GE Free" if they contain less than 0.1 percent GE plants. However, some companies could try to differentiate their products by putting "GE Free" labels on products that cannot be GE. Therefore, if no GE variety of a given plant species is allowed for use in the EU, the products derived from this species cannot be labelled as "GE Free."
- For animal products, two thresholds are set and must be indicated on the label: 1) under 0.1 percent is labeled as "fed without GE plants (0.1 percent)," and 2) under 0.9 percent as "fed without GE plants (0.9 percent)."
- Processed animal products, milk and eggs can be labelled as "sourced from animals fed without GE plants (0.1 or 0.9 percent)."
- For apiculture products, biotech plants should be no closer than three kilometers to an apiary.

For processed products that contain several ingredients, the rules above apply to the ingredients themselves. "GE Free" can be written in the list of ingredients, after the name of the ingredient concerned. It can also be placed on the front of the product but only if this ingredient accounts for at least 95 percent of the dry weight of the product.

It is forbidden to state that the products have a better nutritional, health or environmental value because they are GE free.

• Voluntary Private Initiatives

Some food manufacturers and retailers voluntarily label their products as "GE Free." Such labels are mainly found on animal products (meat, dairy products, and eggs), canned sweet corn and soybean products.

h) MONITORING AND TESTING

Monitoring and testing is performed randomly by government agents on food products, feed products, seeds and crops in order to make sure that GE products approval and labeling regulations are met. In addition, GE products on the market must be monitored by the holder of the approval in order to detect any potential non-intentional effects. ¹⁸

i) LOW LEVEL PRESENCE POLICY

In 2011, the European Commission put in place a tolerance of 0.1 percent for unauthorized GE products in feed. This tolerance applies to GE products authorized for commercialization in a non-EU country and for which an EU authorization request has been lodged with EFSA. It does not apply to food and seeds.

j) ADDITIONAL REGULATORY REQUIREMENTS

French legislation subjects the cultivation of GE crops to transparency rules. The location where GE

¹⁸ For more information, see the interministerial <u>website (in French)</u> dedicated to biotech products regulation

crops are being grown must be declared to the government and this information is entered into a national register, available online.¹⁹ This rule has been controversial, since this public register has been used by activists to locate and destroy open-field trials of GE crops.

French lawmakers therefore established a dual penalty system whereby not declaring the location of GE crops is punishable by a 30,000 euro fine and six months of incarceration, and the destruction or degradation of authorized GE crops is punishable by a 75,000 euros fine and two years of incarceration. The destruction or degradation of GE crops that were planted for research purposes is punished by a 150,000 euros fine and three years of incarceration. However, in practice, court decisions have varied widely and the penalties have not deterred activists from destroying open-field trials of GE crops.

In addition to informing the government authorities, a GE farmer is required to notify the farmers of surrounding land of his intention to plant GE crops, prior to sowing.²¹

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

France supports the plant certificate system²² under the International Union for the Protection of new Varieties of Plants (<u>UPOV</u>), rather than the patent system.

On March 25, 2015, the Enlarged Board of Appeal of the European Patent Office ruled that plants or seeds obtained through conventional breeding methods were patentable. ²³ The French seed industry deplores this decision. They advocate that patents should only be allowed for biotechnological inventions. They state that "this decision allows patenting of native genes. Varieties that possess this characteristic will not be freely accessible. Genetic progress will be hindered." They underline that this decision contradicts the breeder's exemption, which allows free use of a protected variety for further breeding under the plant certificate system.

On July 20, 2016, the Parliament adopted a bill on biodiversity that limits the patentability of living organisms in France:

- <u>Article L611-19 (in French)</u> of the Code of Intellectual Property now states that "products obtained exclusively through essentially biological processes, the elements that compose them and the genetic information they contain" are not patentable.
- <u>Article L613-2-3 (in French)</u> of the Code of Intellectual Property now states that when a plant obtained through essentially biological processes has the same characteristics as a patented biological material, the patent does not apply to this plant.²⁴

These article apply to patents, not to plant variety protection certificates.

¹⁹ Rural Code art. L663-1 (in French)

²⁰ Rural Code art. L671-14 and L671-15 (in French)

²¹ Rural Code <u>art. L663-1 (in French)</u>

²² In French: Certificat d'Obtention Végétale (COV)

²³ European Patent Office's <u>decision</u>

²⁴ In French: "La protection conférée par un brevet relatif à une matière biologique dotée, du fait de l'invention, de propriétés déterminées ne s'étend pas aux matières biologiques dotées de ces propriétés déterminées, obtenues indépendamment de la matière biologique brevetée et par procédé essentiellement biologique, ni aux matières biologiques obtenues à partir de ces dernières, par reproduction ou multiplication."

1) CARTAGENA PROTOCOL RATIFICATION

The Cartagena Protocol on Biosafety (CPB) aims to ensure the safe handling, transport, and use of living modified organisms. France signed it in 2000 and ratified it in 2003. Regulations implementing the CBP are in place.

The competent national authorities are:

- the Ministry of Higher Education and Research;
- the Ministry of Ecology;
- the Ministry of Economy;
- the National Agency for Food, Environmental and Occupational Health (ANSES);
- the Ministry of Agriculture.

Focal points for France are in the Ministry of Ecology and Sustainable Development (Biosafety Clearing House Focal Point) and Ministry of Foreign Affairs (Cartagena Protocol on Biosafety National Focal Point, Convention on Biological Diversity National Focal Point).

For more information, see France's profile on the CBP website.

m) INTERNATIONAL TREATIES AND FORUMS

As a member state of the EU, France's position in international organizations is generally expressed as similar to that of the EU.

France is a member of several international organizations dealing with food and plants like most importantly the Organisation for Economic Cooperation and Development (OECD), the Food and Agriculture Organization of the United Nations (FAO), the European and Mediterranean Plant Protection Organization (EPPO), and Codex Alimentarius. France takes an active role in these fora regarding biotechnology.

PART C - MARKETING

a) PUBLIC/PRIVATE OPINIONS

Some decision-makers are concerned with the precedence of politics over science.

On February 21, 2017, the National Assembly voted a "Resolution on Science and Progress in the Republic (in French)." They deplore that "scientific expertise is not enough taken into account in political decision-making" and ask the government to give more importance to the recommendations of scientific academies and the Parliamentary Office for the Evaluation of Scientific and Technological Choices. They advise decision-makers to look at the benefits and risks of both adopting a technology and rejecting it.

Anti-biotech activists continue their actions against research and imports.

Anti-biotech groups have a long history of opposing the cultivation, importation, and consumption of GE crops and products in France. Their actions include the systematic destruction of test plots, the destruction of imported soybean products, and regular communication campaigns. Many of these actions have led to arrests and criminal charges against them. Courts decisions have varied widely, with results ranging from acquittals to prison sentences.

Although biotech opponents are usually considered small in number, their communication skills are topnotch and amplified by the media. They strongly influence public opinion. Moreover, the public opinion generally expresses distrust of biotech companies that are the most visible. Academic and public research exists but is less visible.

Activists used to destroy crops produced through transgenesis (both commercial crops and field trials). Now that the area planted in GE crops has fallen to zero, they focus on:

- Herbicide-resistant plants produced through classical mutagenesis. Activists destroyed test plots of mutagenesis produced herbicide resistant rapeseed or sunflower in April 2015, August, September, and November 2016, January and April 2017. (see Part B Policy,
 Innovative Biotechnologies).
- Innovative biotechnologies. (see <u>Part B Policy</u>, e) <u>Innovative</u> <u>Biotechnologies</u>).
- Imports of GE feed. Activists destroyed imported GE soy stocked in French ports in 2010, 2012, 2014, and 2016. Their political messages usually insist on the link between soy cultivation and deforestation in South America.
- Public awareness of possible agricultural applications of innovative biotechnologies is low.

There is low awareness about possible agricultural applications of innovative biotechnologies among the general public. Since 2016, the mainstream media has covered actions of anti-biotech groups but almost never explained the possible applications of innovative biotechnologies for agriculture and food production. Medical applications of genome editing and the ethical questions they raise are much more publicized than agricultural applications. Most journalists focus on risks rather than opportunities. CRISPR-Cas9 has the highest media coverage.

• The Government says it differentiates between two categories of biotech plants.

The French government differentiates between what it calls "first generation" and "second generation" biotech plants. The "first generation" includes herbicide and insect resistant plants, which the government opposes. The "second generation" consists of "crops that bring consumer or environmental benefits," with for instance enhanced nutritional content, reduced nitrogen use or improved water efficiency, which the government says it does not oppose.

In February 2015, during the closing speech of a Forum on Agriculture and Climate Change held in Paris, the President of France expressed his position as follows: "Consumers in France and in Europe are opposed to the cultivation of first generation GE plants. They see threats to health and to the environment without sufficient benefits to counterbalance the risks. That is why France and the European Union have adopted a clear and firm position, including in the negotiation of the Transatlantic Trade and Investment Partnership. It is a societal choice and a matter of food sovereignty. However,

researchers in Europe and in France should be able to do their work and to advance science. Public research has to be free in Europe within the limits established by law and it should not fear intimidation, pressure and threats. We need research to feed the world, fight climate change, and produce better." Both public and private researchers deplore the absence of field trials and the threats they face from anti-biotech activists.

a) MARKET ACCEPTANCE/STUDIES

Acceptance of GE crops in France must be looked at from the differing points of view of producers, consumers, and retailers.

Feed grain producers in France, especially corn producers, generally support the use of GE varieties, due to the proven yield gains and lower production costs. French farmers were allowed to cultivate Bt corn between 2005 and 2007, and most of them welcomed the technology. However, due to negative consumer perceptions, acceptance of biotech cultivation is lower among producers in other sectors where the products are consumed directly, such as vegetables and fruit.

Market acceptance of GE products is high in the animal production sectors and in their feed supply chains, including animal feed compounders, as well as poultry, swine and cattle farmers who depend on imported soybean products to make balanced animal feeds.

In France, consumer attitudes towards GE products are strongly negative, with concerns about the potential risks of cultivating and consuming the products. In a 2012 survey, 79 percent of French people said they were "worried" about the presence of GE products in food, and 71 percent thought that they represented "a significant risk in terms of food safety." ²⁵ However, most of surveyed believe that continued research is needed on this subject. ²⁶

As a consequence of consumers' negative perceptions, food retailers, especially major supermarkets, market themselves as carrying only non-GE products. They also fear that if they carry GE products, they will attract actions by activist organizations, such as protests and destruction of products in stores, which would generate negative publicity. The food industry is also developing initiatives that aim at reducing the use of GE feed. For instance, Fleury Michon, which accounts for 20 percent of ham sales in supermarkets in France, has been working with farmers since 2015 to produce premium ham from pigs fed 100 percent non-GE feed.

CHAPTER 2 – ANIMAL BIOTECHNOLOGY

PART D – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

France uses animal biotechnology and cloning in research units:

• To study diseases. Animal models of human diseases are produced by biotechnologies, such as genome editing and genetic engineering.

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Source: <u>IFOP (in French)</u>Source: <u>CSA (in French)</u>

- To produce tissues or organs from GE pigs (xenotransplantation).
- To produce proteins of pharmaceutical interest (blood factors, antibodies, vaccines) in the milk
 of mammals or in egg white produced by hens. Proteins can also be produced by animal cells inlab.
- To improve animal breeding.

b) COMMERCIAL PRODUCTION

No GE animals for food use are commercialized in France. A French company, <u>Cryozootech</u>, clones sport horses, in collaboration with Italian industry.

c) EXPORTS

Cryozootech has exported some horse clones.

d) TRADE BARRIERS

Public and governmental opposition limits the use of products obtained through animal biotechnology and cloning.

PART E - POLICY

a) REGULATORY FRAMEWORK

France operates under the biotechnology regulatory framework of the EU. For more information about the European framework, please refer to USDA <u>EU-28 Agricultural Biotechnology Annual</u> report.

i. Responsible government ministries

Several ministries are involved in oversight of animal biotechnology and cloning in France. The Ministry of Agriculture regulates the techniques used for food production purposes. The Ministry of Ecology is in charge of environmental issues. The Ministry of Research covers public research programs. The Ministry of Health is involved in human health issues.

The High Council for Biotechnology is in charge of environmental risk assessment, while the Agency for Food, Environmental and Occupational Health and Safety (ANSES) is in charge of food safety risk assessment.

Since October 2015, the HCB has been working on an evaluation of the risks and benefits of GE mosquitoes from scientific, technical, sanitary, environmental and socio-economic perspectives. GE mosquitoes could be used to prevent the transmission of human diseases.

ii. Political factors influencing regulatory decisions

ANSES has conducted an analysis and concluded that cloning is not an issue in terms of food safety. France's Government is opposed to using biotechnology and cloning in animal breeding for food production purposes due to ethical and animal welfare concerns.

iii. Legislations and regulations with the potential to affect U.S. trade

The regulation in place in France is that of the EU.

France asked the European authorities to put in place a moratorium on clones and their products intended for food use and a system of traceability and labeling of the products derived from offspring of clones, in line with the position of the European Parliament.

In 2008, the official French Advisory Committee on Food (CNA) to the Ministry of Agriculture released a report on the consumption of products derived from cloned animals and their offspring.²⁷ This report recommended a ban on the marketing of food products derived from cloned animals or their offspring, cloning practices for breeding, and importing cloned animals and their offspring.

b) INNOVATIVE BIOTECHNOLOGIES

France has no regulation in place regarding the use of innovative biotechnologies in animals.

On March 29, 2017, the French Parliamentary Office for the Evaluation of Scientific and Technological Choices (Office parlementaire d'évaluation des choix scientifiques et technologiques, OPECST) released a draft pro-science report on innovative biotechnologies (see <u>Chapter 1, Part B, e) Innovative Biotechnologies</u>). Given agricultural biotechnology is a highly politicized and very sensitive subject and the continued influence of anti-biotech groups in France, it is unlikely all of the recommendations will be implemented. However, they will be looked at by many decision makers and may lead to positive developments in the future. As far as animal biotechnology is concerned, the recommendations of OPECST are the following:

- Supporting research on mosquitoes and other disease carriers, including on gene drive;
- Promoting biotechnology to fight vector-borne diseases but banning species extinction; making recall mechanisms mandatory for any genetic modification of mosquitoes;
- Creating an approval process at EU level for environmental releases; making decisions based on detailed evaluations taking into account environmental risks and public health benefits;
- Requiring reporting on any project that modifies mosquitoes to the World Health Organization, which would then evaluate the project;
- Asking the United Nations Environment Programme to conduct a study on impacts on biodiversity:
- Initiating a North-South dialogue on innovative biotechnologies to fight vector-borne diseases;
- Amending the Cartagena Protocol on Biosafety to take innovative biotechnologies into account.

c) LABELING AND TRACEABILITY

Laboratory animals developed through biotechnology are all labeled and traced and are not released into

²⁷ See the <u>summary of the report, in English</u> or the <u>full report, in French</u>

the environment.

Cloned sport horses are released into the environment.

d) INTELLECTUAL PROPERTY RIGHTS

The regulation in place in France is that of the EU.

e) INTERNATIONAL TREATIES AND FORUMS

As a member state of the EU, France's position in international organizations is generally expressed as similar to that of the EU.

France is a member of several international organizations dealing with food and animals like most importantly the Organisation for Economic Cooperation and Development (OECD), the World Organization for Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO), the European and Mediterranean Plant Protection Organization (EPPO), and Codex Alimentarius. France takes an active role in these fora regarding biotechnology.

PART F - MARKETING

a) PUBLIC/PRIVATE OPINIONS

France's livestock industry does not favor the commercialization of GE animals and clones for food or agricultural purposes, but is interested in animal genomics and marker assisted selection for animal breeding.

Animal rights and anti-meat activists are becoming increasingly vocal in France. For instance, in May 2017, a group called "butchery abolition" broke into a public research center that works on livestock genetics, "released" animals and sprayed the building with false blood. They publicized their actions on social networks and posted a letter stating that the lab was "sequestrating thousands of individuals for eugenics tortures," which they called "a crime against animality." They added: "We, citizens, are making a complaint for sequestration, torture, genocid, eugenic crime, rape, natalist crime, fattening, state terrorism."

b) MARKET ACCEPTANCE/STUDIES

Although GE animals and clones are not in commercial channels, the market acceptance is low among producers and consumers. The acceptance of clones offspring is also low.

There is low awareness of research on GE insects such as mosquitoes and GE olive flies among the general public.